

REMARKS

Prior to entry of the present amendment, claims 1-25 were pending in the application. Claims 1, 2, 10-12, and 15 are currently under examination. Claims 1, 2, 10-12, and 15 are rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. Claims 1, 2, 10-12, and 15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for insufficient antecedent basis. Claims 1, 2, 10-12, and 15 are further rejected under 35 U.S.C. § 103(a), as being unpatentable over Gong et al. (CN 1303689 A, Abstract; hereafter “Gong”) in view of Cai (CN 1223119 A, Abstract; hereafter “Cai”), Li et al. (CN 1074611 A, Abstract; hereafter “Li”), Zhang (CN 1240143 A, Abstract; hereafter “Zhang”), Jenkins et al. (*Packaging Drugs and Pharmaceuticals*, pg. 59, 1993; hereafter “Jenkins”), and Beckman (*The Nature, Action and Use of Drugs*, pg. 38, 1961; hereafter “Beckman”). Claims 1, 2, and 12 are also objected to for informalities.

Claim Amendments

Claims 1, 10, and 12 have been amended and claim 2 has been canceled. Support for the amendment is found, for example, in original claims 2 and 18.

No new matter has been added by the present amendment. Applicant reserves the right to pursue any canceled or withdrawn subject matter in this or in a continuing application.

Claim Objections

Claims 1 and 2 are objected to for failure to italicize the genus and species names of the plants. Claim 12 is objected to for the spelling of the words “flavours” and “colourings.” Claims 1 and 12 have been amended, and claim 2 has been canceled. These objections are now moot.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 1, 2, 10-12, and 15 are rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement, based on factors including the breadth of the claims and the presence of working examples.

In an effort to expedite prosecution, Applicant has amended the claims to specify a particular composition, which lists the specific plant parts for each herb. As such, the amended claims are now directed to compositions that contain extracts of Chi Shao (*Paeonia obovata*) root, Dang Gui (*Angelica polymorpha*) root, Chuan Xiong (*Ligusticum wallichii*) root, Xiang Fu (*Cyperus rotundus*) rhizome, Yan Hu Suo (*Corydalis turtschaninovii*) rhizome, Tao Ren (*Prunus persica*) seed, Fu Ling (*Poria cocos*) sclerotium, Ze Xie (*Alisma plantago-aquatica*) rhizome, Bai Zhu (*Atractylodes macrocephala*) rhizome, Ji Xue Teng (*Spatholobus suberectus*) root and stem, Wu Yao (*Lindera Strychnofolia*) root, and Gan Cao (*Glycyrrhiza uralensis*) root.

References to intended use have been removed from the claims, to have the claims comply with U.S. claim style and because the intended use does not limit the contents of the composition.

Applicant submits that, given the teachings of the specification, one skilled in the art would have been able to practice the claimed invention, without undue experimentation. For example, the specification teaches a specific example of the claimed composition (see Table 2); methods of preparing the composition, including the amounts of each herb making up the composition (page 12, line 1 to page 13, line 3); and methods for preparing different formulations of the composition (page 13, line 5 to page 16, line 14).

The specification further teaches preferred dosages of the composition for treating or alleviating the symptoms of endometriosis, adenomyosis, or dysmenorrhea. For example, the specification teaches the administration of 5 g to 30 g (equivalent raw herb dosage) per day (page 11, lines 4-9). The specification further teaches that the exact dose of the composition administered may vary based on the severity of the gynecological disorder and the health of the patient (page 11, lines 6-7), and that preferred dosages are 5 g to 10 g (equivalent raw herb dosage) administered twice a day and 10 g (equivalent raw herb dosage) administered once a day (page 11, lines 7-9).

The specification further contains data showing the therapeutic efficacy of administration of the claimed composition for the alleviation of symptoms of endometriosis, adenomyosis, and dysmenorrhea. Example 7 of the specification (page 20, line 6 to page 21, line 18) describes a case study of the use of the claimed composition for the treatment of a 24-year old female

presenting with several symptoms of endometriosis (e.g., primary dysmenorrhea involving the abdomen, thighs, and lower back; dyspareunia; abdominal bloating and distension; hot flashes; thirst; palpitations; and a menstrual cycle that was typically 21 days and a period of 6-7 days with medium heavy bleeding). In the study, the claimed composition was administered to the patient in the morning and evening. At the first follow-up appointment (i.e., the second consultation) the patient reported that she experienced *no endometriosis pain* and reduced abdominal bloating and fewer palpitations (page 21, lines 9-13).

Applicant submits that, given the teachings of the specification, one skilled in the art would have been able to practice the claimed invention without undue experimentation and, thus, respectfully requests that this rejection be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 1, 2, 10-12, and 15 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for insufficient antecedent basis. Claim 1 has been amended to remove the phrase “the herbs.” This rejection may now be withdrawn.

Rejection under 35 U.S.C. § 103(a)

Claims 1, 2, 10-12, and 15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gong, in view of Cai, Li, Zhang, Jenkins, and Beckman. As the basis for the rejection, the Office states that “since each of the references teach Chi Shao (*Paeonia obovata*) root, Dang Gui (*Angelica polymorpha*) root, Chuan Xiong (*Ligusticum wallichii*) root, Xiang Fu (*Cyperus rotundus*) rhizome, Yah Hu Suo (*Corydali turtschaninovii*) rhizome and Tao Ren (*Prunus persica*) seed are effective ingredients in compositions for treating gynecopathy...it would have been obvious to combine these plants with the expectation that such a combination would be effective in treating gynecopathy” (Office Action, page 15; Emphasis original). Applicant submits that Gong in view of Cai, Li, Zhang, Jenkins, and Beckman fails to teach the invention of amended claim 1.

In particular, amended claim 1 specifies novel and non-obvious combinations of herbs that include a core base of herbs, plus additional herbs that have been found to be beneficial and improve the side effects from the treatment of adenomyosis, endometriosis, and dysmenorrhea (Table 2). This combination allows enhanced healing and recovery from surgical treatment of these disorders, and is beneficial to patients who react poorly to surgery (see pages 5 and 6 of the specification). As is discussed in more detail below, the presently claimed combination of herbs is not disclosed, taught, or suggested in the cited references, alone or in combination. Further supporting non-obviousness of the claimed compositions is the results obtained by use of the compositions (see examples in the application).

More specifically, the amended claims are now directed to compositions containing Chi Shao root, Dang Gui root, Xiang Fu rhizome, Yan Hu Suo rhizome, Tao Ren seed, Fu Ling sclerotium, Ze Xie rhizome, Bai Zhu rhizome, Ji Xue Teng root and stem, Wu Yao root, and Gan Cao root. Applicant submits that none of Cai, Li, Zhang, Jenkins, nor Beckman disclose compositions including Fu Ling sclerotium, Ze Xie rhizome, Bai Zhu rhizome, Ji Xue Teng root and stem, and Wu Yao root.

According to the Office, Gong discloses the use of cyperus rotundus root, Chinese angelica root, ligusticum root, corydalis tuber, and licorice for the treatment of gynecopathy; Cai discloses the use of red peony root, Chinese angelica root, nutgrass flatsedge rhizome, corydalis tuber, and licorice for the treatment of irregular menstruation, menstrual molimen, and female infertility; Li discloses the use of Chinese angelica, red peony, and peach seed for the treatment of oviduct obstruction; and Zhang discloses the use of peach kernel, Chinese angelica root, ligusticum root, cyperus root, and fennel fruit for the treatment of female infertility. Gong and Beckman do not disclose any plant extracts or parts, and teach only information on formulations. As none of Cai, Li, Zhang, Jenkins, nor Beckman disclose, suggest, or provide any motivation to make compositions including Fu Ling sclerotium, Ze Xie rhizome, Bai Zhu rhizome, Ji Xue Teng root and stem, or Wu Yao root, this rejection should be withdrawn.

CONCLUSION

Applicant submits that the application is now in condition for allowance, and such action is hereby requested.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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Susan M. Michaud
Susan M. Michaud, Ph.D.
Reg. No. 42,885

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045